

## **REMARKS**

Claims 1 – 30 are pending in this application.

Claims 1 – 30 have been rejected.

Claims 1, 9, 17 and 24 are currently amended.

### **Entry of Amendment**

This amendment is entered pursuant to 37 C.F.R. 1.116(b)(2) to place the application allowable or in better condition for appeal. An advisory action is earnestly solicited.

### **Amendments to the Claims**

Claims 1 and 17 have been amended to remove the word “uniformly” at lines 12 and 9, respectively. These amendments cure a rejection under 35 USC § 112, first paragraph, for failing to comply with the written description requirement arising out of a prior amendment adding “uniformly”. No new matter has been added.

Claims 9 and 24 have been rewritten in independent form, with claim 9 incorporating the subject matter of claims 1 and 2, from which claim 9 previously depended, and claim 24 incorporating the subject matter of claims 17 and 18, from which claim 24 previously depended. Claims 9 and 24 have been further amended to incorporate a separator zone between the first tapered zone and the second tapered zone. This amendment is supported in paragraph [0016] of the specification, and Figures 3 and 4. No new matter has been added.

### **Rejections Under 35 U.S.C. § 112**

Claims 1 – 30 have been rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. Claims 1 and 17 have been amended to remove the word “uniformly”, thereby reciting a “gradual decrease” in diameter in the taper zone. In view of the dictionary definition of “taper” being, in pertinent part, “a

gradual decrease in thickness or width of an elongated object” (*The American Heritage Dictionary of the English Language, Fourth Edition*, Houghton Mifflin Company, 2000, p. 1769) it is submitted that “gradual decrease” in diameter is an inherent characteristic of any taper zone. Thus, it is respectfully submitted that in view of these amendments, claims 1 – 30 should no longer be rejectable under 35 USC § 112, first paragraph, and the rejections should be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

Claims 1 – 30 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,498,482 (“Williams ‘482”). These rejections, over the claims as amended, are respectfully traversed.

Williams ‘482 discloses a transvenous pacing lead having an improve stylet. The stylet has a taper which results in a soft tip that “complies with the curvatures and bends of transvenous pacing lead” (column 1, lines 53 – 55). The stylet is configured to “allow for easy insertion and control around the curves and bends of the lead” (column 3, lines 19 – 20). Thus, Williams ‘482 discloses that the stylet should conform to the curves and bends of the lead. As such, not only does Williams ‘482 not show, disclose or suggest a stylet with a pre-formed j-shape that imparts a similar curve to the lead, William ‘482 teaches away from a stylet with a pre-formed j-shape that imparts a similar curve to the lead by specifically disclosing that that it is the stylet that conforms to the lead.

By contrast, claims 1 and 17 recite a pre-formed j-shape stylet that imparts a similar curve to the lead. Williams ‘482 does not show, disclose or suggest a pre-formed j-shape stylet that imparts a similar curve to the lead, and, as has been noted above, actually teaches away from a pre-formed j-shape stylet by asserting that the stylet conforms to the lead. Thus, Williams ‘482 does not show, disclose or suggest all of the subject matter of claims 1 and 17.

The Office Action asserts “it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stylet of Williams with a j-shaped stylet in order to yield the predictable results of reducing trauma to the

arterial system.” It is respectfully submitted that this statement does not capture the requirements to show obviousness under the Examination Guidelines after the *KSR* decision. There has been no finding of each claimed element in the prior art. There has been no finding of a simple substitution of some components with other components. Nor has been no finding of a base device that has been improved in the same way. There has been no finding that a base device has been “improved” by a technique known in the art. There is no showing that it would have been obvious to try a pre-formed j-shape stylet. There has been no finding that the prior art included a similar or analogous device. And finally, not only has there not been a finding of a teaching, suggestion or motivation in Williams ‘482 for a pre-formed j-shape stylet that imparts a similar curve to the lead, Williams ‘482 teaches away from that by asserting that the stylet conforms to the shape of the lead.

Williams ‘482 does not show, disclose or suggest all of the subject matter of claims 1 and 17. Nor does Williams ‘482 meet any of the Examination Guidelines for determining obviousness under *KSR*. Thus, it is respectfully submitted that the rejection of claims 1 and 17 under 35 USC § 103(a) as being obvious over Williams ‘482 is improper and should be withdrawn.

Claims 5 – 7 each contain additional patentable subject matter and depend from claim 1, while claims 21 – 23 each contain additional patentable subject matter and depend from claim 17, and as such incorporate all of the subject matter of the claims from which they depend. Because claims 5 – 7 and 21 – 23 contain additionally patentable subject matter and because the rejection of claims 1 and 17 are improper, it is respectfully submitted that the rejections of claims 5 – 7 and 21 – 23 under 35 USC § 103(a) as being obvious over Williams ‘482 are improper and should be withdrawn.

Claims 2 – 4 and 8 depend from claim 1, and claims 18 – 20 depend from claim 17. While the Office Action states that claims 2 – 4, 8 and 18 – 20 have been rejected, it does not state on what particular grounds the rejection is based. Therefore, it is respectfully submitted that the rejections of claims 2 – 4, 8 and 18 – 20 are improper. Claims 2 – 4, 8 and 18 – 20 each contain additional patentable subject matter. Because of

the additionally patentable subject matter and because the rejections of claims 1 and 17 are improper, it is respectfully submitted that the rejections of claims 2 – 4, 8 and 18 – 20 under 35 USC § 103(a) as being obvious over Williams '482 are improper and should be withdrawn.

Claims 9 and 24 have been rewritten in independent form, but previously depended from claims 1 and 17, respectively. While the Office Action states that claims 9 and 24 have been rejected, it does not state on what particular grounds the rejection is based. Therefore, it is respectfully submitted that the rejections of claims 9 and 24 are improper. In addition to the subject matter of claims 1 and 2 and 17 and 18, respectively, claims 9 and 24 further recite a second taper zone. Williams '482 does not show, disclose or suggest a second taper zone. Thus, Williams '482 does not show, disclose or suggest all of the subject matter of claims 9 and 24. It is respectfully submitted that the rejections of claims 9 and 24 under 35 USC § 103(a) as being obvious over Williams '482 are improper and should be withdrawn.

Claims 13 – 15 depend from claim 9, and claims 28 – 30 depend from claim 24, and as such incorporate all of the subject matter of the claims from which they depend. Claims 13 – 15 and 28 – 30 each contain additional patentable subject matter. Because of the additionally patentable subject matter and because the rejections of claims 9 and 24 are improper, it is respectfully submitted that the rejections of claims 13 – 15 and 28 – 30 under 35 USC § 103(a) as being obvious over Williams '482 are improper and should be withdrawn.

Claims 10 – 12 and 16 depend from claim 9, and claims 25 – 27 depend from claim 24. While the Office Action states that claims 10 – 12, 16 and 25 – 27 have been rejected, it does not state on what particular grounds the rejection is based. Therefore, it is respectfully submitted that the rejections of claims 10 – 12, 16 and 25 – 27 are improper. Claims 10 – 12, 16 and 25 – 27 each contain additional patentable subject matter. Further, because of the additionally patentable subject matter and because the rejection of claims 9 and 24 is improper, it is respectfully submitted that the rejections of

claims 10 – 12, 16 and 25 – 27 under 35 USC § 103(a) as being obvious over Williams  
'482 are improper and should be withdrawn.

## Summary

In view of the amendments made and arguments presented, claims 1 – 30 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.


## Correspondence

**All correspondence should continue to be directed to:**

**Medtronic, Inc.  
710 Medtronic Parkway NE  
Minneapolis, MN 55432-9924.**

Respectfully Submitted,

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William D. Bauer  
Registration No. 28,052

IPLM Group, P.A.  
Broadway Place West, Suite 6600  
1300 Godward Street NE  
Minneapolis, Minnesota 55413-1741  
Telephone: 612-331-7405  
Facsimile: 612-331-7401